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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,471	07/05/2001	Zeren Gao	00-46	3433

7590 11/26/2002

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/26/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,471

Applicant(s)

GAO, ZEREN

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 14, 15, 16 in part, and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

Applicant's election of Group II invention in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Further, applicant indicate that claims 1-7, 14, 15, 16 in part, and 17-20 are *withdrawn* from consideration, which is improper as applicant may *cancel*, but may not withdraw claims.

Currently, claims 1-20 are pending, and claims 8-13 and claim 16 in part are under consideration. Claims 1-7, 14, 15, 16 in part, and 17-20 are withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Claim 16 is objected to for encompassing a non-elected subject matter, the isolated polypeptide of claim 1. The claim is further objected to as it depends from a non-elected claim. The applicant is required to amend the claim to read only upon the elected invention, and to depend from an elected claim.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-13 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, and specific, or a well-established utility.

Claims 8-13 and 16 are directed to an isolated nucleic acid encoding a polypeptide having SEQ ID NO:2, or the splicing variant thereof having SEQ ID NO:5, a vector and a host cell thereof, a method of recombinant expression of such, and a composition comprising said nucleic acid. The encoded polypeptides are a putative cytokine receptor, and designated Zcytor14.

The specification discloses a nucleic acid of SEQ ID NO:1 encoding a murine cytokine receptor of SEQ ID NO:2 or 5. Based on the sequence study, Zcytor14 polypeptides share

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sequence homology to the known human IL-17 receptor. Accordingly, the specification asserts, at page 70 (the last paragraph), that polypeptide having Zcytor14 activity can be used to treat inflammation, and conditions such as rheumatoid arthritis, that are associated with inflammation (as IL-17 and IL-17R do). Additionally, the specification asserts the use of Zcytor14 nucleotide sequences to provide Zcytor14 for treatment; a therapeutic expression vector comprising a molecule such as the anti-sense, or a ribozyme to inhibit Zcytor14 gene expression (page 75, lines 25-28), and the production of transgenic mice (page 79, the last paragraph).

The asserted utilities are not considered to be specific and substantial because the specification fails to provide specific support therefor, such as information about a particular functional activity, biological significance of Zcytor14 polypeptide, or any known ligand for the putative cytokine receptor of the instant invention.

Generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a known protein. For example, IL-18 receptor (IL-18R) was thought to be another IL-1 receptor (IL-1R) base on the sequence homology, and therefore, designated IL-1 receptor-related protein (IL-1Rrp) when it was first discovered, and its ligand was unknown (Parnet et al., J. Biol. Chem., 1996, 271(8): 3967-70). IL-1Rrp is now known as IL-18R, has distinct ligand, and possesses distinct function from IL-1R even though it is a member of IL-1R family. Additionally, Skolnick et al. (Trends in Biotechnology, 2000) teaches that because proteins can have similar structures but different functions, determining the structure of a protein may not necessarily reveal its function (see entire article, especially Box 2). Therefore, an established utility for IL-17 and IL-17R cannot be automatically applied to "Zcytor14" polypeptide without functional analysis, especially given the fact that the ligand of Zcytor14 is not known. While it might be possible that the Zcytor14 protein is a member of IL-17R family, that by itself does not suggest any specific or substantial utility for the reasons above.

The disclosed uses for the nucleic acid in producing the polypeptide, gene therapy, and as a pharmaceutical composition are not specific and substantial in the absence of knowledge of the ligand which said receptor binds, any biological property of the receptor protein, or any disclosed gene mutation, or any disease or condition which could be so diagnosed, or treated. Therefore,

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there is no immediately evident patentable use for the claimed Zcytor14 polypeptide or nucleic acid encoding such. Upon further research, a specific, and substantial utility might be found for the claimed isolated polynucleotides and protein. This further characterization, however, is part of the act of invention, and until it has been undertaken, the claimed invention is incomplete.

Until a specific and substantial utility can be attributed to the IL-17RL polypeptide or the nucleic acid encoding such, or a credible disease association established, uses such as generating transgenic animals, are not considered by the Patent Office to be a specific or substantial utility, as such uses could be asserted for *any* DNA.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-13 and 16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial or credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Prior Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ruben et al. (WO9958660 – A1) discloses a nucleic acid (locus AAZ65269) encoding a human polypeptide, which comprises amino acid residues 1-467 of SEQ ID NO:2 of the instant case with 81% sequence similarity, and amino acid residues 1-491 of SEQ ID NO:5 of the instant case with 85.5% sequence similarity (see computer printout of the search results).

Conclusion:

No claim is allowed.

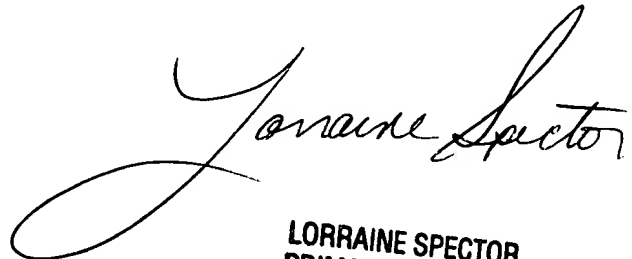
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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
11/18/02